REMARKS

Claims 1-14 are currently pending in the application. By this amendment, claims 1, 2, 8 and 9 are amended for the Examiner's consideration. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

<u>It is respectfully requested that the Examiner reconsider the applicant's prior request to contact the undersigned to discuss bringing this case into condition for allowance. See the last page of these remarks.</u>

The Examiner maintains rejection of claims 1-6 and 8-13 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,129,403 to Henriquez et al. ("Henriquez") in view of U.S. Patent No. 5,919,144 to Bridger et al. ("Bridger"). Henriquez discloses a method and apparatus for detecting acoustic signals originating in a brain, such as those that characterize intersaccular aneurysms (abstract). This detection is accomplished by an acoustic matching medium pressing against the eye socket, providing an acoustic path between the brain and the detector that is inherently low loss (abstract).

There is no suggestion in Henriquez for measurement of intracranial pressure (ICP). Nor is there any suggestion in Henriquez to apply an external audio signal to the skull in order to induce responses in the brain. It will be recalled, earlier in the prosecution of the present case, that the Examiner sought to provide the ICP connection missing from Henriquez by means of the Yost reference, which described a measurement of skull expansion to measure ICP. However, it was not obvious that one skilled in the art would connect Yost and Henriquez, since Yost's measurements were of the skull and, furthermore, connecting the invention's measurement apparatus to the skull – which has a much different impedance than the brain, resulting in signal loss – would make the invention inoperable.

The Examiner cites Bridger to provide the ICP measurement element missing from Henriquez. However, more is missing from Henriquez than the general concept of ICP measurement. Bridger discloses non-invasive measurement of ICP using acoustic signals in the audible and sub-audible ranges. These acoustic signals are transmitted from mountings on the head, being coupled at various locations to the head so that the "sound ... ensonifies the cranial cavity through the skull" (col. 6, lines 2-4) or, alternatively, by contact "which directly ensonifies the skull and thereby the parenchyma" (col. 6, lines 6-7). The acoustic content is optimized by "a coupling fluid for contact-type transmitters and receivers, or by a sealed air volume for air-coupled type transmitters and receivers" (col. 5, lines 38-41). The measurement of the results of these acoustic signals may be accomplished by a) separate receivers mounted on the head (e.g. item 18 shown in Figure 1) "preferably at locations where the parenchyma can be ensonified through the skull" (col. 5, lines 44-45) or b) by using the same element "to transmit instantaneously and subsequently receive" in repeated cycles (col. 5, lines 47-49). In another embodiment "the acoustic signal transmitter may use a localized fluid filled calibrated pressure mini-chamber attached to the skull" (col. 6, lines 57-59) where "small increases in ICP couple to the fluid in the chamber such that the chamber pressure is increased" (col. 6, lines 59-61).

An acoustic signal transmitter as an embodiment of the Bridger disclosure is shown in Figure 2 and described in detail at col. 7, line 18, to col. 8, line 13. It is clear that Bridger uses the skull through which to transmit and receive acoustic signals, noting the coupling advantage provided at the temples where the skull is thin and "determination of the parenchymal properties are least effected (sic) by the skull" (col. 6, lines 32-34).

It will be noted that the present invention relies upon the impedance match along the path between the brain and the eye. This impedance match is known in the art, as described in the background section of the present invention, as a "window ...

for seeing brain pressure" because ICP is "DIRECTLY communicated" to the eye (page 2, lines 8-11). As described in Henriquez,

> "Unfortunately, the skull, being very rigid compared to surrounding fluid and soft tissues, constitutes both a damping and reflective barrier for [acoustic wave] signals. Consequently, any detection system that attempts to detect acoustic signals after they have traversed the skull will inherently have a poor signal to noise ratio and poor sensitivity" (col. 1, lines 26-32).

However, as indicted above, Bridger adopts an approach that relies upon detection <u>through the skull</u>. Note further that, according to the operation of the present invention, it is important to avoid contact of the eye sensor with the skull via the eye socket (page 10, lines 1-5).

<u>It is not disclosed in the combination of Bridger and Henriquez that the approach of Bridger is operable at the resonance frequency of the eyeball (33-43kHz), which is in the ultrasonic range.</u> <u>**Indeed, the evidence provided by Henriquez is that the Bridger technique of through-the-skull measurement "will inherently have a poor signal to noise ratio and poor sensitivivy." Consequently, one skilled in the art would not follow the Bridger teachings outside the disclosed evidence, which is limited to very low frequencies**</u>. It will be observed that all of Bridger's data (Figures 3 and 4; Table 1 in col. 10)) are in the range 0-1kHz, and Bridger indicates a preference for this range (col. 3, lines 20-24; col. 8, lines 3-4; col. 9, lines 64-65: "The frequency range of 10 to 1,000 Hz yielded particularly useful resonance and attenuation data"). Further, Bridger's disclosure touts "unexpected low frequency resonances" (col. 4, line 29) attributed to audio wave stimulation of "the fine structures within the cerebral vascular bed" (col. 4, lines 17-35). <u>**It would have been clear to one skilled in the art at the time of the invention that through-the-skull techniques of Bridger would only be operable at very lower frequencies. This point is confirmed by the teachings of Henriquez, which specifically reject the Bridger through-the-skull approach**</u>**.**

The Examiner admits that Henriquez does not specify an ultrasonic range at which the device is to operate, and relies upon Bridger's **mere mention of such a range, unsupported by the evidence. One skilled in the art would not find a "teaching" in such a mere mention without evidence. The absence of supporting evidence in the Bridger reference is a strong indication that the Examiner's use of this mere mention is based upon hindsight**.

Further, absent impermissible hindsight, one skilled in the art would infer that Bridger's operability depends upon the **disclosed detection techniques tailored to the skull** and therefore not applicable to the eye. These techniques are significant and substantial. For example, Bridger is aware of the "reflective barrier" (Henriquez, col. 1, line 27) provided by the skull. In order to deal with this, Bridger discloses a "gating method" for screening such "reflections or spurious signals" using a time window (col. 6, lines 19-23). One skilled in the art, carefully reflecting upon Bridger's disclosure, would be directed toward low frequency techniques for detection through the skull. Henriquez avoids the skull entirely, and says nothing about use of a supplied signal because Henriquez is simply interested in **detection of existing signals in the brain**. Consequently, Bridger does not provide one skilled in the art with a basis for combination with Henriquez.

What the Examiner is doing here is putting thoughts in the mind of one skilled in the art at the time of the invention, thoughts that suggest a combination that would not have been evident to one skilled in the art. The combination that is suggested to the Examiner, with the benefit of hindsight, but would not have been suggested to one skilled in the art at the time of the invention, is the use of impedance matched detection over a range of frequencies to cover resonance. Neither Bridger nor Henriquez address or suggest the eye resonance pressure effect used by the present invention (page 8, lines 24-25). Brain pressure increases are transmitted directly and – because of impedance matching – without signal loss, to the eye.

It is at the eye, using non-intrusive eyelid sensors, where the damping effects can be measured most noticeably, i.e. “The largest difference between the natural and the damped frequencies is near the resonant frequency”, at a resonant frequency of the eyeball, which is in the range of 33-43kHz (page 8, line 11, to page 9, line 20). The independent claims 1 and 8 have been further amended to clarify this point, with corresponding amendments in claims 2 and 9. It should be appreciated that the title of the invention includes “INTRA OCULAR” as well as “INTRA CRANIAL PRESSURE.”

The Examiner notes that Henriquez discloses gaining acoustic signal information about the brain, but does not disclose gaining ICP measurements from acoustic signal information. It is worth noting that Henriquez measures acoustic signals generated within the brain itself, whereas the present invention (and Bridger) are concerned with measuring the effect of the brain upon acoustic signals <u>applied to the brain</u>. As noted above, the Examiner concedes that Henriquez “does not specify an ultrasonic range at which the device is to operate” (OA, page 3).

The Examiner asserts that it would have been obvious to one skilled in the art to modify the Henriquez device to accommodate the acoustic signal frequencies used in the Bridger device, in order to measure intracranial pressure. However, from what has been said above, one skilled in the art would not read Bridger – given the limitations of the Bridger data to the range 0-1kHz (Figs. 3 and 4, and Table 1) – to disclose anything at all about the use of ultrasonic frequencies to determine ICP. Thus, it is not clear what the motivation would be for this connection. The Examiner asserts the motivation “to provide a device and method which can measure intracranial pressure without skull penetration, which poses minimal health risks to a patient during long term monitoring.” This argument fails to make the logical linkage upon which the Examiner is resting his argument. In the first place, the problem of finding a non-invasive ICP measurement procedure was well known in the art. Furthermore, the question about health risks to the patient relates to the deficiencies

of prior art ultrasonic approaches which require high power to achieve "usable signal-to-noise ratios", as described in the background section of Bridger (col. 1, lines 41-65). It was for this reason that Bridger pursued <u>lower frequencies</u> (and data limited to the 0-1kHz range). The Examiner's argument is an explanation why Bridger seeks to use lower frequency acoustic signals, not why one skilled in the art would apply Bridger to Henriquez.

Furthermore, precisely because Bridger measures acoustic frequencies at the skull <u>and</u> is expressly concerned with the added power requirements required to obtain "usable signal-to-noise ratios," the Bridger disclosure directs one skilled in the art to lower frequency ranges of 0Hz to 1kHz (col. 8, lines 3-4), where power requirements are reduced. However, at these frequencies the wavelengths are so long there would be large phase effects, as would be appreciated by one skilled in the art. This is another reason against using the Bridger technology. Based on the Bridger disclosure, one skilled in the art would not see a practical way to modify Henriquez using Bridger. While Bridger does provide ICP detection, so did the Yost reference. Just as one skilled in the art would fail to connect the Yost technology to Henriquez, so one skilled in the art would fail to connect the Bridger technology to Henriquez.

As with Yost, Bridger relies upon measurements taken at the skull. As one skilled in the art would appreciate, the impedance at the skull is much different than the impedance of the brain. The teachings of Bridger are directed toward acoustic signal detection (and corresponding analysis) that is operable <u>because of the lower frequencies that avoid power problems</u> notwithstanding the use of detectors that "listen" through the skull. It is noteworthy that Bridger identifies the temple region, where the skull is relatively thin and the effects of the skull are thereby reduced. Nonetheless, Bridger claims to be able to achieve high sensitivity (col. 11, lines 9-10) using through-the-skull measurements. It should be emphasized that Bridger <u>has no data above the range of 0-1kHz</u>, a fact which would be significant to one skilled in the art. While he cites "acoustic frequencies under 100kHz" this is an obvious "shot

in the dark" to cover the possibility that **<u>his "through the skull technique</u>** could yet be found useful at high frequencies. One skilled in the art would have no difficulty seeing this as mere speculation not supported by evidence, and would <u>not</u> see this as a "teaching" even as to Bridger's technique and certainly not a "teaching" of ultrasonic frequency use by techniques not even mentioned in Bridger. Bridger's <u>preference</u> is for 0-20kHz, <u>more preferably</u> for 1-10kHz, and <u>most preferably</u> 50-500Hz (col. 3, lines 2024; col. 8, lines 3-4). Thus it is clear that Bridger's technique zeroes in on the lower frequencies. There is no suggestion in Bridger that his through-the-skull acoustic transmitters and receivers would be suitable for an application as described in Henriquez. Nor does Henriquez provide any suggestion regarding ICP measurements or the externally applied acoustic signals that would then be measured <u>at resonance</u> to determine ICP. Henriquez says nothing at all about resonance.

It has long been understood that the eye provides a "window to the brain", in the sense that there is an acoustic impedance match between the brain and the tissues leading to the eye and the eye-lid. Henriquez documents this prior art teaching, but does not provide additional teachings that would connect up to ICP measurement technology. Instead, Henriquez uses the well known "window to the brain" teaching to pursue determinations of the source of acoustic signals "originating in a brain" (abstract) that indicate "the presence of life threatening conditions such as aneurysms in time to treat them safely" (col. 2, lines 27-28). The contribution made by Henriquez goes in a different direction than would be required for one skilled in the art to make a connection between Henriquez and the ICP measurement technology of Bridger (or the present invention).

What the present invention provides – and claims as novel and non-obvious – is a method and apparatus for applying acoustic signals to the brain across the skull, measuring the damping of these signals at a resonance frequency of the eyeball, using an acoustic eye patch, and analyzing the acoustic eyepatch output to determine ICP. While Henriquez detects brain generated acoustic frequencies via the eye, there is no

suggestion of either ICP or use of eyeball resonance frequencies, which are in the ultrasonic range. Bridger measures ICP, but does so through the skull and discloses resonance limited to the low frequency 0-1kHz range. Henriquez is silent on resonance, and is silent in particular regarding the resonance of the eyeball. Bridger does not address <u>**the resonance of the eyeball, which resonance is at frequencies well above operable frequencies for which Bridger discloses data**</u>. The independent claims have been amended to make explicit the limitation to "a resonant frequency of said eyeball." The eyeball resonance frequencies (33-43kHz) are ultrasonic and above the highest range (0-20kHz) preferred by Bridger. On a careful reading of Bridger, <u>one skilled in the art would not assume that data limited to the range 0-1kHz would provide an operable teaching for ultrasonic frequencies, especially where Bridger itself complains about the debilitating power requirements of ultrasonic frequencies</u>. The gap between Henriquez and Bridger is too large for one skilled in the art to arrive at the present invention, except through impermissible hindsight.

The Examiner has also rejected claims 7 and 14 under 35 U.S.C. §103(a) as being unpatentable over Henriquez in view of Bridger and further in view of U.S. Patent No. 5,951,477 to Ragauskas et al. ("Ragauskas"). The Henriquez/Bridger combination is not an adequate reference, as explained above, and therefore this further ground of rejection is also overcome. Furthermore, Ragauskas is a 1999 patent that discloses using an ultrasonic Doppler device measuring "internal and external blood velocities of intracranial and external cranium portions of the optic artery." This does not disclose the measurement of arterial pulsations claimed by the present invention.

In view of the foregoing, it is requested that the application be reconsidered, that claims 1-14 be allowed, and that the application be passed to issue.

It is noted that the Examiner did not respond to the applicant's prior request to call the undersigned if the application was found to be other than in condition for

allowance. That request is respectfully renewed, notwithstanding the finality of this rejection. The undersigned may be reached at 703-787-9400 (fax: 703-787-7557; email: clyde@wcc-ip.com) to discuss any other changes deemed necessary to bring this application into condition for allowance.

If a further extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Sincerely,

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